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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,042	02/19/2002	Walter Messier	GENO200.1/CIP	5992

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,042	MESSIER, WALTER	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *1-30,37-44,51,52 and 54-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-36, 45-50, and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) (8 pages) Paper No(s)/Mail Date 10/21/03; 9/16/03; 9/15/03; 3/4/03; 5/9/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election with traverse of Group II, claims 31-36, 45-50, and 53 in the reply filed on 07/14/04 is acknowledged. The traversal is on the ground(s) that serious search burden would not apply to Groups 2 and 5-10, as Groups 5-10 are directed to various EG307 polynucleotides and so the search for Group 2 would necessarily be coextensive with the search for Groups 5-10. This is not found persuasive because it is unclear what is encompassed in the genus "EG307" polynucleotide, polypeptide, or gene; further, as set forth in the restriction requirement, each individual sequence must be searched independently of the others and is therefore considered as a separate invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-30, 37-44, 51, 52, and 54-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/14/04.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed (EG307 nucleic acids and related products/methods).

4. The specification is objected to because of the following informality: the continuation information at the beginning of the specification must be updated to indicate issue of parent application 09/875,666 as US Patent No. 6,743,580.

5. Claims 31-36, 45-50, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) These claims are confusing because it cannot be determined what is encompassed by an "EG307" polynucleotide or polypeptide. The specification discloses certain specific polynucleotides and polypeptides according to various SEQ ID NO identifiers, and it is unclear what polynucleotides/polypeptides other than those defined by said identifiers might be included in the scope of the claims. In other words, the skilled artisan cannot determine whether polynucleotides/polypeptides having various degrees of sequence similarity, or functional similarity, satisfy the language of "EG307". Clarification is required.

B) Claim 34 is further confusing because "the EG307 gene" lacks proper antecedent basis.

C) Claim 35 is further confusing because of the language "recombinant polynucleotide". While this terminology is well known in the art, it is used in many different contexts, and thus it is unclear what is contemplated in the claim.

D) Claim 36 is confusing because it is drawn to a method, but depends from "polynucleotide" claim 34. Correction is required.

E) Claim 47 is further confusing because of the language "encoding and EG307 gene". Correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

7. Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This claim is drawn to a hypothetical, chemically- and physically-undefined "agent" which might be identified by the method of claim 46. Applicants were clearly not

in possession of any such "agent" at the time of filing, and there is no basis for performing a patentability search for such an "agent". In Technology Center 1600 claims of this type are referred to as "reach-through" claims, as protection is sought for subject matter which is not in possession at the time of filing an application, but might possibly be obtained at some time in the future.

8. Claims 31-36, 45-50, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to subject matter encompassing a genus of nucleic acids/polypeptides referred to as "EG307".

The proper inquiry in the instant situation is: is there a representative number of species implicitly or explicitly disclosed, such that one of ordinary skill in the art would understand applicant to be in possession of the claimed genus? Firstly, as pointed out above, this inquiry cannot be fully applied as it is unclear what in fact is to be included in the genus of "EG307" polypeptides/polynucleotides. Even if it were assumed that this genus contains all plant polypeptides/polynucleotides having a certain degree of homology with disclosed polypeptides/polynucleotides having specific SEQ ID NOs, and it is considered that several species within this genus are disclosed in the specification, it is submitted that the answer to this inquiry is in the negative, and thus that the written

description requirement for the claimed genus is not satisfied. In other words, it is believed that applicant's disclosure of several plant "EG307" polynucleotides/polypeptides is insufficient to support possession of such polynucleotides/polypeptides from the entire very large genus of all plants.

Other relevant considerations are as follows:

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the disclosed SEQ ID NOs, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the disclosed SEQ ID NOs, but not the full breadth of the claims, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant, encompassing related nucleic acids with potentially different functions/properties, such as encoding polypeptides with different properties, or providing hybridization probes of different specificities among a range of different target organisms. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is separable from its enablement provision. (See page 1115.)

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-36, 45-47, 49, 50, and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Chory et al. (US 6,245,969).

These claims are drawn to "EG307" polynucleotides, methods of expressing them, and transgenic plants or plant cells comprising them. As noted above, it cannot be determined what is encompassed by "EG307", but the specification indicates this refers to a "yield-related gene" (page 29, line 16).

Chory et al. disclose Bin1, a plant gene related to yield, and methods of genetically modifying a plant with Bin1 to increase yield, as well as assays for identifying agents which affect Bin1 (see entire patent, especially column 2, lines 12-34; columns 12-18; columns 22-27). Bin1 of Chory et al. cannot be distinguished from "EG307" in the instant claims.

10. Claim 48 is free of the prior art, but is rejected for other reasons. No claims are allowable.

11. Concibido et al. (US 2002/0157143) is made of record as a reference of interest.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kenneth R. Horlick, Ph.D.
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Primary Examiner
Art Unit 1637

09/21/04